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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,155	12/21/2000	Sylvie Rouquier	19904-008	9730

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ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,155

Applicant(s)

ROUQUIER ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 March 1105.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RP

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 03/11/05, have been entered in full.

Response to Amendment

Applicant is notified that the text of the statutes relied upon as the bases for the following claim rejections can be found in a prior Office action.

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 101

Claims 1, 2, 4-8 and 11 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth in the prior Office action.

Applicant arguments regarding the alleged membership in the family of OXR proteins have been fully considered but not deemed persuasive. There is no single substantial utility that is commonly shared among the members of the family of OXR proteins. Specifically, Applicant argues that olfactory receptor members enable animals to smell and that this is a substantial utility. This argument has been fully considered but not deemed persuasive. There is no teaching, ^{for example,} as to which molecule(s) of tens of thousands of possible ^{scent?} molecules the polypeptide encoded by SEQ ID NO: 224 enables an animal to smell. One would need to know ^{what molecules activate OXR} this before

The determination of such constitutes part of the act of invention.

Although it is clear that OXR plays a role in the sense of smell, it is not clear what that role is.

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one could begin to use the claimed polynucleotide in a way that might constitute a substantial utility.

Applicant argues that the screening assays discussed on page 273 provide a specific and substantial utility. This argument has been fully considered but not deemed persuasive. As stated previously, the instant specification puts forth that the polypeptide is useful in a screening method to determine what ligands may activate or inhibit the polypeptide and also to determine what the physiological effects of the polypeptide might be (see page 273). This proposed use lacks a specific and substantial utility. It is not a specific use because any integral membrane protein could be used in exactly the same way. Further, many polypeptides are known in the art, yet the polypeptides have no known function or known ligands. Any of these orphan clones could be used in the manner described in the specification for the claimed polypeptide.

Furthermore, the proposed use of the polypeptide to screen for ligands of the polypeptide or for biologic effects of the polypeptide is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be.

Applicant cites Roqueir et al., PNAS 97(2870-4)2000 as providing evidence that the polynucleotide of SEQ ID NO: 224 could be used as a research tool to ascertain the olfactory ability of mammalian species, as the ratio of OR genes to pseudogenes has been shown to correlate with such ability. This argument has been fully considered but not deemed persuasive. While Applicant's hypothesis is of interest from a scientific perspective, it does not provide a

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basis for a practical utility that meets the requirements of a well established or otherwise substantial utility. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”

It is admitted in Roqueir et al. that the concept of comparing olfactory abilities between mammals is not well developed and controversial e.g. Roqueir state:

“However, it is difficult to measure and compare the olfactory efficiency of different animal species. Various parameters such as the threshold of detection of odorants (sensitivity), the range of odors detectable, and the discriminatory power (acuity) are key parts of the olfactory ability. Thus, it is difficult to determine precisely which of these parameters are taken in account when comparing two species, and therefore the origin of the olfactory deficiency of primates remains controversial and difficult point to address”, see the last paragraph of col 1 of page 2873 bridging to the second column.

Thus, Applicant's asserted use of the polynucleotides does not appear to be a well ^{substantial} established utility as it is not refined and developed to the point where specific benefit exists in currently available form.

Claims 1, 2, 4-8 and 11 are also rejected under 35 U.S.C. § 112 first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art

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would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

Additionally, as set forth previously, should Applicant establish a substantial utility as required by 35 U.S.C. 101, the potential scope of enablement rejection, argued by Applicant, would apply to claims 1, 2, 4-8 and 11 which encompass variants of SEQ ID NO: 224.

Applicant's arguments regarding compliments of varying length, mismatches and stringency have been substantially addressed previously. Applicant's arguments regarding Wands analysis have been fully considered but not deemed persuasive. It appears that that all of the factors, A-G, listed by Applicant are relevant, and have been discussed in prior office actions. Particularly A, the breadth of the claims is relevant. The claims are extraordinarily broad e.g. they encompass a number of different embodiments, that for practical purposes is essentially limitless and nor are they constrained by any functional limitations. Also it should be pointed out that there do not appear to be any working examples of artificially constructed variants of a polynucleotide of 224. Regarding Applicant's arguments regarding the specificity of stringent conditions, the issue is that the specification has failed to teach how to make any variant of SEQ ID NO: 225 with any particularly useful property and nor has the specification taught how to use variants that do not have any particularly useful property.

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Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

A handwritten signature, possibly reading 'V7', is located below the 'MB' text.

May 9, 2005

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER